



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/510,488

03/28/2005

James Browning

MPA-003

1575

22832 7590 04/28/2009
K&L Gates LLP
STATE STREET FINANCIAL CENTER
One Lincoln Street
BOSTON, MA 02111-2950

EXAMINER

BURK, CATHERINE E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/510,488 | Applicant(s) BROWNING, JAMES | |
| | Examiner CATHERINE E. BURK | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>30 March 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the amendment submitted on March 20th, 2009. The Examiner acknowledges the cancellation of claims 1-31 and 34, the amendments to claims 32 and 33, and the addition of new claims 36-39. Examiner also acknowledges the omission of claim 33 in the original office action (mailed December 23rd, 2008), because of that oversight, this action is non-final.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 38 recites the limitation "the second surgical tape" in line 2. There is insufficient antecedent basis for this limitation in the claim. This limitation also appears in claim 39.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

Art Unit: 3735

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 32 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter (US 6830052 B2).

6. Carter discloses a method of supporting a urethra comprising: providing a surgical tape - 120- comprising a supporting zone interposed between first and second ends and being about 15 cm in length (col. 7, lines 9-12) (claim 36); introducing the tape into at least one incision made on an upper wall of the vagina -12-; inserting the first end of the tape behind a first side of the urethra -16- (fig. 12 and col. 7, lines 22-25) and fixing the first end into the tissues of the retropubic space (col. 7, lines 20-22) without penetrating the rectus sheath (fig. 11 and col. 2, lines 54-56). The same steps are repeated on a second side of the urethra with the second end of the sling such that the supporting zone passes under the urethra (fig. 13 and col. 7, lines 28-34).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 33, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter in view of Neisz (US 2002/0161382 A1).

9. Claims 33 and 37; Carter discloses a method of transmitting intro-abdominal pressure to the urethra comprising: providing first -90- and second -92- surgical tapes, each comprising first and second ends, introducing the first tape into an incision made on an upper wall of a vagina -

Art Unit: 3735

12- and behind a first side of the urethra -16-; fixing the first end of the first tape into the tissues of the retropubic space, above the endopelvic fascia -22- (fig. 7) without penetrating the rectus sheath (fig. 6 and col. 2, lines 54-56); locating the second end of the first tape alongside the urethra and inserting the second end into the sub-urethral pressure compartment, below the endopelvic fascia (fig. 9 and col. 6, lines 41-49). This process is repeated for the first and second ends of the second surgical tape.

10. Carter fails to disclose the tape is preferably between 2-8 cm, however Neisz discloses a tape for insertion under a urethra and fixation within the retropubic space that is preferably less than 4 inches in length (~10cm) [0083] (claim 37). Since Neisz lists 10 cm as a preferable maximum length of the tape, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a tape of approximately 4-8 inches in Carter's method because it is within the optimal range provided by Neisz for a tape with anchors in the retropubic space and passing under the urethra [0027].

11. Claims 38 and 39; Carter fails to disclose securing the tape within the retropubic space using bone anchors with tooth-like projections or glue. However, Neisz discloses a number of embodiments for securing the first and second ends of the tape to the tissues of the retropubic space including tissue anchors with tooth-like projections (figs. 18, 19, 26, or 29) (claim 38) or a glue (fig. 30, [0034 and 0120]) (claim 39).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to use bone anchors with tooth-like projections or a glue, as disclosed by Neisz, to secure the ends of the tape disclosed by Carter within the retropubic space because Neisz discloses that when disturbed by an implantable material, such as an anchor or glue, the retropubic space will

Art Unit: 3735

generate a tough fibrous tissue, providing substantial holding power for an implant placed in that space [0025].

Response to Arguments

13. Applicant's arguments, see pages 5 and 6, filed March 20th, 2009, with respect to the rejection(s) of claim(s) 32 under Kovac have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Carter. Carter discloses implantable tape materials that are implanted and anchored in the retropubic space and below the endopelvic fascia.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention. Ulmsten (US 2002/0128670 A1) also discloses a surgical tape implanted in the retropubic space using an adhesive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 8:30 AM - 6:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. E. B./
Examiner, Art Unit 3735